

Remarks

Priority

Independent claim 1 is directed to a rigid, solid support which is a bead and which comprises (A) an antibody that specifically binds to CD28 and (B) an MHC class I- immunoglobulin complex. The MHC class I immunoglobulin complex comprises (1) two fusion proteins, (2) two MHC class I β_2 microglobulin polypeptides, and (3) two immunoglobulin light chains. Each of the two fusion proteins comprises an MHC class I α chain comprising a peptide binding groove and an immunoglobulin heavy chain comprising a variable region. The Examiner contends that priority application Serial No. 60/395,781 does not support fusion proteins which comprise "the entire MHC class I alpha chain and the entire Ig heavy chain, not just the extracellular regions or the Ig hinge and constant regions, respectively."

The present claims are entitled to the filing date of Serial No. 60/396,781. Figure 1 of Serial No. 60/395,781, which is reproduced below, depicts each feature of the recited MHC class I immunoglobulin complex, including fusion proteins which comprise the entire MHC class I alpha chain and the entire Ig heavy chain.

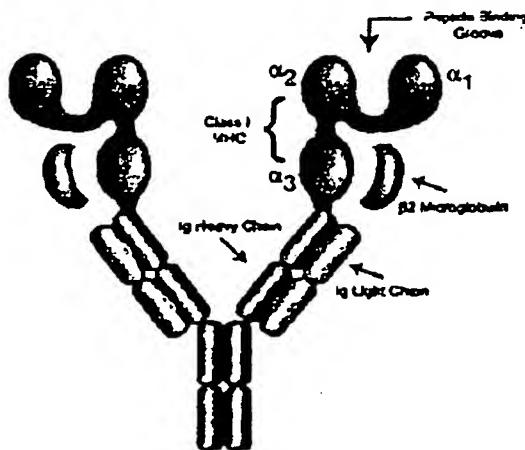


Figure 1 Schematic of HLA-A2-Ig

Obviousness Rejections over U.S. Patent 6,266,411 in view of Pardigon

Claims 1, 12-15, 48, and 49 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent 6,266,411 in view of Pardigon *et al.*, *J. Immunol.* 164, 4493-99, 2000. Claims 1, 12-15, 48, and 49 also stand rejected over claims 1-34 of the '411 patent in view of Pardigon. Applicants respectfully traverse the rejections.

An obviousness-type double patenting rejection is analogous to an obviousness rejection under 35 U.S.C. § 103 except that the disclosure of the cited patent is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 600, footnote 4, 154 U.S.P.Q. 29, 34, footnote 4 (C.C.P.A. 1967). Thus, the double patenting analysis parallels an analysis under 35 U.S.C. § 103(a). *In re Braat*, 937 F.2d 589, 592, 19 U.S.P.Q.2d 1289, 1291-92 (Fed. Cir. 1991). The two obviousness rejections are rebutted together below.

The Examiner cites the '411 patent as disclosing the subject matter of claim 1 except that the '411 patent does not disclose a bead comprising an anti-CD28 antibody. The Examiner cites Pardigon as teaching the use of anti-CD28 antibodies to stimulate antigen-specific CD8+ T cells. The Examiner contends it would have been *prima facie* obvious to one of ordinary skill in the art to have modified the rigid solid support disclosed in the '411 patent to include anti-CD28 antibodies.

Pardigon discloses short-term expansion of antigen-specific CD8⁺ T cells, *i.e.*, only transient activation of the cells. In contrast, the claimed solid support causes long term expansion of antigen-specific CD8⁺ T cells. In particular, after ten days of culture in the presence of the claimed support the number of antigen-specific CD8⁺ T cells increases seven fold. The number of activated antigen-specific CD8⁺ T cells is also maintained for a long period of time in culture. As the Declaration of Drs. Jonathan Schneck and Mathias Oelke filed April 3,

2008 under 37 C.F.R. § 1.132 explains, it was surprisingly unexpected that beads with the features recited in claim 1 supported large scale expansion of antigen-specific CD8⁺ T cells. See Example 4 in the present specification and paragraphs 11-13 of the Declaration.

There is no suggestion, either in Pardigon or anywhere in the record, that the combination of the anti-CD28 antibodies and the recited MHC class I-immunoglobulin complex would provide a long-term expansion of antigen-specific CD8⁺ T cells. The recited subject matter is therefore not *prima facie* obvious over the '411 patent (or claims 1-34 of the '411 patent) in view of Pardigon. Please withdraw the rejections.

Proposed Rejection over Claims 1-104 of the '411 Patent

The Office Action asserts that claims 1-104 of the '411 patent could form the basis for a rejection of the pending claims under 35 U.S.C. § 103(a) in view of Pardigon if the '411 patent qualified as prior art under 35 U.S.C. §§ 102(e), (f), or (g) and if the conflicting inventions were not commonly owned at the time the invention claimed in this application was made.

Statement concerning common ownership

Both the present application Serial No. 10/618,267 and U.S. Patent 6,266,411 were, at the time the inventions of Serial No. 10/618,267 were made, subject to an obligation of assignment to The Johns Hopkins University.

There is, therefore, no basis for a rejection under 35 U.S.C. § 103(a) based on the '411 patent as prior art under 35 U.S.C. §§ 102(e), (f), or (g).

Respectfully submitted,

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